REMARKS/ARGUMENTS

Current Status of Claims Remaining in the Application

Claims 1-3, 5, 6, 13 and 15 remain in the application. All other claims have been cancelled.

Claim 1 has been amended to add limitations and all of the other claims depend from claim 1.

Overview

The present invention is directed to a fluid tight seal for a sterilization container having a filter system that has the advantages over other systems known in the art of preventing fluid within the container or fluids outside of the container from traversing the container walls through the seal. In addition, this important function of the seal is maintained over time by protection afforded the seal gasket by the invention's novel arrangement of parts.

Applicant directs the Examiner's attention to the "Summary of Invention" section in Applicant's response dated February 4, 2008, which is incorporated herein as if fully set forth. The thrust of that summary is that the claimed invention is directed to <u>a seal</u> in a sterilization container. This is significant since, as demonstrated in Applicant's previous response, and as demonstrated again below, the structure in the primary reference, Williams, is not a seal (and cannot, under any technically recognized definition, be fairly called a seal). In addition, it follows, and is a fact, that the structure relied on as the basis of the rejection cannot function as a seal. And as would be expected from the

above, Williams does not teach or suggest that the structure in question is, or could function as, a seal.

The features of the invention that impart its unique function as a seal are a matching recess and ridge, a gasket disposed entirely within the recess for protection, and a disposition of parts that places the ridge and gasket in compression with the filter therebetween.

Applicant will demonstrate below that the prior art relied on to reject the claims does not anticipate Applicant's invention as set forth in the pending claims, and the claims as now amended are allowable.

Specification Amendments

The specification has been amended to overcome the listed objections and to support the current claim language without introducing any new matter. All of the amended matter is either already described in similar terms and/or clearly shown in the drawings.

As regards the second paragraph of page 4 at line 5, Applicant has corrected the amendment indication of the holes by reference "234," which should be "24".

Similarly, at page 5, second paragraph, line 6, the "vent 11" has been correctly identified by the number "23".

Claim Rejections - 35 U.S.C. §112

As regards the assertion that the specification does not disclose that the seal is formed around both the container vent and the cover vent, Applicant respectfully disagrees. While it is true that the gasket technically only surrounds the container vent, the seal that is formed between the ridge and the recess surrounds both vents when the parts are operatively engaged.

As regards the space between the cover vent and the container vent not being referenced in the specification (although it is clearly shown in the drawings), Applicant has amended the specification to make reference to this disclosed feature.

The lateral movement of sterilization media is, as explained in the specification as amended, necessary since the holes of the two vents are not aligned, thus requiring sterilization media to move laterally in order to pass through a hole in one vent to a hole in the other vent.

Applicant does not fully understand the rejection under 35 U.S.C. 112 to claim 15. The vent planar member described in claim 1 could be in the lid container or any other container planar member that forms the external members of the container. Claim 15 merely states that the planar member is specifically in the container lid, as opposed to one of the other container members.

Claim 1 has been amended to provide an antecedent basis for "the container planar member".

Claim 1 has also been amended to make it clear which of the two vents is being referred to.

Claim 4 has been cancelled.

Claim 6 has been amended to overcome the 112 rejection.

Accordingly, Applicant respectfully submits that all of the rejections based on 112 have been cured by amendments or explanation.

111

Claim Rejections - 35 U.S.C. §103

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (4,915,913) in view of Lorenz (4,551,311)

The rejection based on Williams and Lorenz that was made against claims 1-12 in the previous Office Action dated October 4, 2007 relied on the elements 50, 52, C, 54, 85, 70 and others, all at the top end of the Williams container. Applicant argued in response that the arrangement of those parts was not for the purpose of forming a seal and, in fact, the parts were so arranged that the cover plate ridge could not engage the vent recess in a manner that could form a fluid tight seal. The Examiner questioned that contention in remarks made in response to Applicant's arguments made after final. (See Examiner's December 11, 2007 remarks.)

In the amendment and remarks made and entered together with the RCE, Applicant pointed out how the Examiner had apparently misread Fig. 5 as an alternative embodiment when, in fact, it was a different view of the same embodiment as Fig. 6. As a result, that ground for rejecting the claims (Williams plus Lorenz) was abandoned and in its place, a "new ground" (as characterized by the Examiner) has been raised. The new ground, however, once again relies on Williams as the primary reference.

The current rejection is again based on Williams and Lorenz, but this time, the Examiner relies on the arrangement of parts at the bottom of the Williams container (elements 60, 6, 85, B, 64, 85 and others). The

vent structure at the bottom of Williams' container is, however, structurally very similar to that at the top that, like the top structure, it cannot form a seal or act as a seal.

Nothing of substance is added to the previous rejection by focusing on the bottom vent rather than the top vent. The barrier plate 60 cannot be forced into compression engagement with bottom member 6 any more than can elements 70 and C. And specifically, recess groove 47 cannot be forced into compression engagement with recess groove 65. On this point, Applicant and the Examiner appear to agree (see current Office Action pages 11-12).

Referring to Figures 4, 6 and 9 of Williams, the barrier plate 60 is held in place by attachment to the side walls 10 and 12. The attachment is by an expansion mechanism that creates a force parallel to the barrier plate (and bottom 6) that wedges the barrier plate 60 between the walls 10 and 12 at a fixed distance from bottom 6. No force is created perpendicular to plate 60 and bottom 6 that would put those members in compression to form a seal.

At Col. 5, lines 23–49, Williams describes the mechanism for attaching the barrier plate 60:

"The lower barrier plate member 60 is provided adjacent to opposed ends with outwardly and slightly upwardly inclined flange portions 66 with one of the flanged portions adapted to be received under an inwardly extending ledge-like shoulder portion 68 (FIG. 4) formed from the material of the sidewall [10] of the case. The other flange portion 66 carries a lever arm 69 (FIG. 9) having an actuating tab 67 which is pivoted, as at 70,

thereto for pivotal movement about a vertical axis. The level arm 69 has a curved cam edge 73 and a linear edge 75 which is adapted to be pivoted under another ledge-like shoulder portion 76 formed from the material of the sidewall [12] of the case. An integral boss 78 (FIG. 9) extends upwardly from the flange portion 66 and is adapted to bias the lever arm 69 upwardly as the lever arm is pivoted transversely toward the ledge-like shoulder portion 76 so as to maintain the linear edge 75 in a resilient retained engagement beneath the ledge-like shoulder portion 76 to prevent dislodgement of the lower barrier plate member 60 relative to the bottom of the case. Accordingly, the flange portions 66 of the lower barrier plate member 60 coact with the ledge-like shoulder portions 68 and 76 via the lever latch 69 so as to retain the lower barrier plate member 60 in a generally resilient, biased locking engagement relative to the bottom of the case until the lever latch is pivoted (arrow) to the open position, as illustrated in dotted line in FIG. 9." (emphasis added).

In Williams, the mechanism that locks the barrier plate 60 in place (see Fig. 9) exerts a force against the shoulder portions 68 and 76 (side walls 10 and 12, respectively) and no force is applied in the direction of the bottom member 6. That the locked-in position of the barrier plate 60 is at a distance from bottom member 6 that prevents engagement between the recess 47 and 65 is manifest from the drawings. Both Figs. 4 and 5 (the only ones that show the relative positions of the barrier plate 60 and bottom member 6) and their respective recess grooves, clearly show the recess grooves to be non-engaged under compression. If they were so engaged, the filter sheet 85 there between would be deformed -

which it is not. The mechanism provided in Williams does not permit the barrier plate 60 to be biased toward the bottom member 6 such that the recess grooves are in compression, forming a seal with filter (a point conceded by the Examiner).

The Examiner has conceded in the past, and concedes again, that the arrangement of parts specified in Williams does not form a seal ("Williams ('913) does not appear to specifically teach . . . that said sheet filter is forced against said gasket to form a seal") (at page 9).

Because Williams fails to teach a seal, it cannot be the basis of a prima facie showing of obviousness as to claims to an arrangement of parts that do form a seal. See *Ex parte Kalliokulju*, 2007 WL 1378833 (BPAI May 10, 2007) (No. 2007-0834, Tech. Ctr. 2100) citing *In re*Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

On that basis alone, all of the rejections must fail as they are all based on Williams as the primary reference.

Thus, to make the rejection, the Examiner has had to reconstruct Williams to create a seal where none previously existed and where none was desired or apparently necessary.

Claim 1 as now amended includes elements that are not found in Williams and not supplied by Lorenz. With reference to Williams, the elements labeled 54 and 77 in Fig. 6 do not and cannot form a seal and are not provided for that purpose. As set forth in Col. 5, starting at line 58, Williams states: "upper barrier plate member 70 has a peripheral recess groove 77 disposed <u>for registration</u> with the corresponding concave surface provided by the recess groove 54 in cover member C, as

aforesaid." Thus, the purpose of elements 54 and 77 in Williams is not to form a seal, but rather merely for purposes of registration only. This is further borne out by the manner in which the barrier plate 60 is attached to the side walls, as discussed in detail above.

In applying Williams, the Examiner states:

"Williams ('913) does not appear to specifically teach that a gasket is secured wholly within said vent recess where it is protected against damage or that said sheet filter is forced against said gasket to form a seal."

In actuality: the recess of Williams is not provided as part of a seal and therefore Williams does not teach or suggest that a gasket be secured wholly within said vent recess (or that a gasket be provided within the recess at all). There being no intent to form a seal, there is no need or reason for a gasket and no need or reason to force said sheet filter into said recess.

In further applying Williams, the Examiner makes the erroneous statement that the various parts of Williams are capable of forming a seal surrounding both the container vent (62, 64) and cover vent (46, 48) (current Office Action at page 6). Applicant has shown above that the filter cover is locked in a position that does not permit the formation of a seal. The Examiner has recognized that the locking mechanism of Williams does not allow the cover to be forced against the filter and vent to form a seal. (Current Office Action at pages 11-12.)

The inability of Williams to permit compression between the cover, the filter and the vent, and the absence of a gasket are consistent with

the fact that Williams does not, at any place in its description, describe those parts as forming a seal or even suggest that they could function as such or that his invention would benefit from doing so. There is certainly nothing on which to assert that Williams teaches a fluid tight seal. Thus, to suggest that all that is missing from Williams to arrive at Applicant's claimed invention is a gasket within one of the recess grooves is both erroneous and an obvious hindsight use of Applicant's disclosure, which, of course, is not permitted.

KSR International v. Teleflex Inc., 550 U.S.____ (2007) (KSR), speaks specifically to this [point where it states:

("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".)

"As is clear from cases such as Adams, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."

"It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (Emphasis added.)

"See Graham, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "`guard against slipping into the use of hindsight'" (quoting Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F. 2d 406, 412 (CA6 1964)))."

Because Williams does not teach a seal, there was no "reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" to

create a seal. The rejection uses non-seal forming parts from Williams together with parts from Lorenz and parts from Gabriel and reconstructs from those diverse parts a seal where none existed in the first place.

If anything, Williams teaches away from Applicant's invention by teaching that the corresponding parts that Applicant's invention put into compression are, in Williams, fixed to a common member and maintained a fixed distance from each other, which prevents compression. To suggest that the parts of Williams could be put in compression, when it serves no purpose in Williams, is to reveal that the impetus for doing so must have come from hindsight reliance on Applicant's disclosure - a basis for combining references prohibited by KSR, supra.

Conclusion

The combination of claim 1 of a protected gasket in a recess in one vent structure, a second mating vent structure having a ridge that registers with and is placed in compression with the first vent structure by the ridge fitting into the recess and forming a fluid tight seal with the gasket, holes in the vent structures that are non-aligned when the vent structures are in registration and a filter space between the vent structures that is, by the structure of the recess and ridge, greater than the thickness of the filter, produces a clear advance in the art by which a safer, more effective and more durable filter seal is provided for a sterilization container.

Because these elements are not found in the prior art in the combination now claimed by Applicant in claim 1 and because the

claimed combination would not have been obvious to one skilled in the art at the time the invention was made, all of the other claims depending from claim 1 are allowable as well.

For all of the reasons set forth above, Applicant submits the claims remaining in the application are allowable and the application is otherwise in condition for allowance.

Respectfully Submitted,

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